09/457,709.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 14, 2006.

David Saliwanchik

David R. Saliwanchik, Patent Attorney



CERTIFICATE OF CORRECTION
Docket No. UF-T391D1
Patent No. 6,976,709



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Applicants | : | Richard J. Melker, Michael J. Banner, Samsun Lampotang, Paul B. Blanch, Neil Russell Euliano, Ronald G. Carovano, Jr. |
| Issued | : | December 20, 2005 |
| Patent No. | : | 6,976,487 |
| For | : | Ventilatory Method Utilizing Body Length-Based Parameter Calculations |

Attention Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below are the column and line numbers where errors occurred in the patent. In the right-hand column are the page and line numbers in the application where the correct information appears.

| **Patent Reads:** | **Application Reads:** |
|---|---|
| Column 2, line 35: | Page 4, line 15: |
| "$(V_1)$" | -- $(V_i)$ -- |

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| **Patent Reads:** | **Application Reads:** |
|---|---|
| Column 3, line 21: | Page 6, line 12: |
| "$(V_1)$" | -- $(V_i)$ -- |
| Column 6, line 62: | Page 15, line 20 |
| "valve **0.70** is" | -- valve **70** is -- |
| Column 8, line 39: | Page 19, line 23: |
| "BLW operation." | -- BUV operation. -- |
| Column 11, line 6: | Page 25, line 30: |
| "water ($cmH_2$)." | -- water ($cmH_20$). -- |
| Colum 11, line 12: | Page 26, line 7: |
| "30 $cmH_{20}$." | -- 30 $cmH_20$. -- |

A true and correct copy of pages 4, 6, 15, 19, 25, and 26 of the application as filed which support the Applicants' assertion of the error on the part of the Patent Office accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

David Saliwanchik

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DRS/ehm
Attachments: Certificate of Correction in duplicate
Copy of pages 4, 6, 15, 19, 25, and 26 of specification



2006

# UNITED STATES PATENT AND TRADEMARK OFFICE
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PATENT NO. : 6,976,487

Page 1 of 1

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ISSUE DATE : December 20, 2005

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Column 2,

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Line 12, "30 $cmH_{20}$." should read -- 30 $cmH_20$. --.

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impractical for use in many environments such as aero-medical transport, in emergency departments, during intra-hospital transport and in hospitals of developing or third world countries.

In the prior devices which are microprocessor controlled or utilize electrically driven gas supplies, an electrical failure can result in an inoperative ventilator. Alternatively, the prior devices, which are pneumatically driven and controlled, lack many of the advanced safeties and features available through the use of modern microprocessor technology.

In addition, these prior devices require the initial parameters, such as tidal volume ($V_T$), ventilatory breathing frequency (f) and inspiratory flow rate ($\dot{V}_i$) to be input by the health care provider. These values are generally determined based on the patients weight and age. In emergency situations the difficulty in accurately determining a patient's weight as well as errors in inputting the parameters can result in improper, even dangerous, ventilator settings. The prior art devices do not provide for safety mechanisms to prevent such occurrences.

## SUMMARY OF THE INVENTION

The present invention relates to a hybrid microprocessor controlled ventilator.

In one aspect of the present invention a ventilator is provided having a ventilation flow rate control device and a controller for adjusting the ventilation flow rate control device. The controller can be

It is an object of the present invention to provide an inexpensive full featured ventilator unit having a "basic" and "advanced" mode that, in the basic mode, can be operated by health care providers having limited respiratory training and that, in the advanced mode, can be operated by skilled healthcare providers as a full featured ICU ventilator.

It is also an object of the present invention to provide a ventilator having an automated ventilation set-up feature for automatically setting the initial values of tidal volume ($V_T$), ventilatory breathing frequency (f) and inspiratory flow rate ($\dot{V}_i$) based upon the patient's length.

It is a further object of the present invention to provide a ventilator having incorporated therein a parameter tracking, independent pneumatic back-up ventilator (BUV). In the event of electrical power failure or failure in the primary electronic ventilator, the ventilator will automatically operate in the back-up mode using solely pneumatic power and the ventilation parameters set prior to the failure.

It is a further object of the present invention to provide a ventilator having an electrical power-independent control system for maintaining continuous positive airway pressure (CPAP). This control system maintains the CPAP, at the level provided prior to electrical power failure, or primary electronic ventilation failure, during BUV operation.

Alternatively, if the ventilator was set to ventilate a pediatric patient a solenoid driven three-way valve 92 will be energized momentarily. Gas is then supplied, through valve 92, from the output line 50 to the selector valve 64. This gas supply will set the selector valve 64 to connect the output line 62 to the pediatric timer 88.

Once set by momentarily energizing one of the valves 90, 92 the selector valve 64 will remain in its set position until reset by energizing the alternate valve 92, 90. In the preferred embodiment the selector valve 64 is a CLIPPARD 302 selector valve.

The adult timer unit 86 and pediatric timer unit 88 are pneumatically driven timers. When in back-up mode the gas supplied through the selector valve 64 drives either the adult timer unit 86 or pediatric timer unit 88.

When ventilating an adult, at intervals determined by the timer unit 86, gas is supplied to open a valve 70. When the valve 70 is open, gas will flow from a supply line 68, which is supplied by output line 62, through the valve 70 and into a check valve 94 where it is then provided to a supply line 96.

Alternatively, if ventilating a pediatric patient, during back-up ventilation, the pediatric timer 88 will supply gas at selected intervals to a valve 72 allowing gas to flow from a supply line 68 to a check valve 98 where it is then provided to a supply line 96.

When the gas supply on supply line 96 ceases, the diverter valve 112 will switch, disconnecting supply line 116 from the exhalation valve charging line 114. A quick release valve 134 is provided to allow the diverter valve 112 to switch rapidly. When the pressure at the input supply line 136 of the quick release valve 134 is greater than that at the output supply line 138 the valve 134 remains closed. When the pressure at the input supply line 136 falls slightly below that at the output, i.e. when gas flow rate on supply line 96 ceases, the quick release valve 134 opens, quickly purging the gas in supply line 138, and allowing the diverter valve 112 to switch.

During primary ventilation mode operation, valve 60 is supplied with gas via supply line 56. When the microprocessor of the ventilator control board 222, FIG. 12, energizes the valve 60, gas flows into the diverter valve 112 and the circuit operates as described above with respect to back-up mode operation. The gas supplied at supply line 116 is provided now through needle valve 140. A check valve 142 is provided to prevent gas from flowing back onto supply line 56 during BUV operation.

An orifice 144, connected to a tap on the exhalation valve charging line 114, is shunted to open air. This orifice 144 provides a constant bleed for pressure in the exhalation valve charging line 114 when that pressure exceeds atmospheric pressure.

positive pressure limit 204. As long as the patient's effort is maintained, the preselected airway pressure remains constant 204, with a variable flow rate of gas from the ventilator. Inhalation cycles "off" 206 when the preselected inspiratory time 208 elapses. The ventilator, thus, is time cycled, following which passive exhalation occurs. With PCV the peak inspiratory flow rate, flow rate wave form, tidal volume, and airway pressure contour depend on the patient's breathing pattern. Tidal volume is determined by the level of PCV, the patient's inspiratory effort, total compliance, and total resistance.

The ninth ventilatory mode, depicted in FIG. 11, is pressure controlled ventilation combined with continuous positive airway pressure (PCV-CPAP). In the PCV-CPAP mode, positive pressure breaths 210, 212 are provided in the PCV mode as described above. During exhalation of the PCV breaths, airway pressure decreases to the preselected CPAP level 214.

In the ventilator of the embodiment of FIG. 1 several of the modes described above may be disabled so that the ventilator operates as a minimally featured transport ventilator. In particular, in the basic mode the ventilator will operate only in the SIMV-CPAP mode. In this mode, an upper limit for CPAP is provided which is substantially below the CPAP level ordinarily allowable. In the embodiment of the ventilator of FIG. 1, the CPAP level can be adjusted to provide a positive pressure in the range of 0 to 5 centimeters of water ($cmH_2O$).

In the advanced mode, ventilation can be provided in each of the nine modes described above. The upper limit on CPAP in the advanced mode can be set substantially above that permitted in the basic mode. In the embodiment of the ventilator of FIG. 1, CPAP can be adjusted to provide a positive pressure in the range of 0 to 30 $cmH_2O$.

The electrical system 216, FIG. 12, of the ventilator device of the embodiment of FIG. 1 consists of a user interface system, power supply system and ventilator control system.

The user interface system includes the user interface control board 218, user interface display board 220 containing LCD drivers, alphanumeric LCD displays 236, alarm indicators 238, switches 240 and a multi-purpose dial.

The power supply system includes a power supply and battery charger board 224 supplies power over line 226 for all the power requirements of the electronics and electrically controlled pneumatics of the ventilator. The power supply, is capable of running from a battery 228 or from AC or DC external supplies 230. The power supply system must be capable of operating over a wide range of AC voltage supplies available worldwide.

The ventilator control board 222 controls all operational logic of the ventilator. As such the ventilator control board 222 controls the operation of the proportional flow rate control valve 58, the solenoid driven valves 54, 60, 82, 90, 92 and 158